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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,266	06/20/2003	Fumitoshi Asai	03337C/HG	7488

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FRISHAUF, HOLTZ, GOODMAN & CHICK, PC
220 Fifth Avenue
16TH Floor
NEW YORK, NY 10001-7708

EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/600,266

Applicant(s)

ASAI ET AL.

Examiner

Brian S. Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 6-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. By Amendment filed 12/01/06, claims 1-2, 6, 9 and 12 been amended and claims 15-19 have been cancelled.
2. Claims 1-5 are currently pending for prosecution on the merits.

Summary of Action

3. The objection of disclosure under 35 USC 132(a) is not maintained in light of the amendment.
4. The rejection of claims 1-5 and 15-19 under 35 USC 112, first paragraph, is not maintained in light of the amendment.
5. The rejection of claims 1-3 under 35 U.S.C. 103(a) as being unpatentable over Ogletree (US 6509348) in view of Bernat et al. (US 5989578) is maintained for the reasons of record.
6. The rejection of claims 4-5 under 35 U.S.C. 103(a) as being unpatentable over Ogletree (US 6509348) in view of Bernat et al. (US 5989578), and further in view of Koike et al. (US 5288726) is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogletree (US 6509348) in view of Bernat et al. (US 5989578).

Bernat teaches a pharmaceutical composition comprising ADP receptor blocking antiplatelet drug (i.e., clopidogrel or ticlopidogrel) in combination with aspirin.

Ogletree teaches a pharmaceutical composition comprising ADP receptor blocking antiplatelet drug (i.e., CS-747 which is 2-acetoxy-5-(alpha-cyclopropylcarbonyl-2-fluorobenzyl)-4-5,6,7-tetrahydrothieno[3,2-c]pyridine, clopidogrel and ticlopidine) or pharmaceutically acceptable salts thereof in combination with thromboxane A2 receptor antagonist and aspirin, wherein the ratio of said ADP receptor blocking antiplatelet drug and aspirin is within the range

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from about 50:1 to about 0.51, preferably from about 25:1 to about 1:1 (see column 4, lines 18-30 and 38-42; column 31, lines 32-37). Ogletree discloses CS-747 as the functional equivalent to other known ADP receptor blocking antiplatelet drug such as clopidogrel and ticlopidine.

Bernat teaches a pharmaceutical composition comprising ADP receptor blocking antiplatelet drug (i.e., clopidogrel or ticlopidogrel) in combination with aspirin.

The teaching of Ogletree differs from the claimed invention in the preparation of said composition "consisting essentially of" 2-acetoxy-5-(alpha-cyclopropylcarbonyl-2-fluorobenzyl)-4-5,6,7-tetrahydrothieno[3,2-c]pyridine and aspirin. To incorporate teaching of Ogletree, would have been obvious in view of Bernat who teaches the routine knowledge in preparing combination of ADP receptor blocking antiplatelet drug and aspirin in absence of thromboxane A2 receptor antagonist

Above references in combination make clear that making combinations of three components, (a) ADP-receptor blocking antiplatelet drug, (b) tromboxane A2 receptor antagonis and (c) aspirin or combination of two components, (a) ADP-receptor blocking antiplatelet drug and (c) aspirin is well known in the art. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

8. Claims 4-5 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogletree (US 6509348) in view of Bernat et al. (US 5989578), and further in view of Koike et al. (US 5288726). See rejection above.

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The modified teaching of Ogletree mentioned above (Ogletree and Bernat et al.) includes all that is recited in claims 4-5 and 18-19 except the use of the specific salt form, namely hydrochloride or maleate.

However, it would have been obvious in view of Koike who teaches compounds represented by formula (I) including 2-acetoxy-5-(alpha-cyclopropylcarbonyl-2-fluorobenzyl)-4-5,6,7-tetrahydrothieno[3,2-c]pyridine, wherein said compounds are prepared in pharmaceutically salts thereof including maleate and hydrochloride (abstract; column 13, lines 43-63; column 22, line 19 and Example 23).

One having ordinary skilled in the art would have been motivated to select the claimed compounds in maleate or hydrochloride salt with reasonable expectation of success that preparation of said composition in maleate and hydrochloride salt form would not significantly alter the analogous properties of compound of the reference due to close structural similarity of the compounds.

Response to Arguments

9. Applicant's arguments and Declaration filed 12/01/06 have been fully considered but they are not persuasive.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the

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applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Patent Examiner
AU 1614

A handwritten signature in black ink, appearing to read 'B. Kwon', with a long horizontal stroke extending to the right.

BRIAN-YONG S. KWON
PRIMARY EXAMINER